

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES  
Antimicrobials Division

September 16, 2003

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF:**  
**Sterilex Ultra Disinfectant Cleaner Solution 1**

**DP Barcode: D293175**

**Manufacturing-use [] OR**

**Reg. No. Or File Symbol: 63761-I**

**End-use Product [X]**

**TO:** Marshall Swindell/Tony Kish  
PM Team No. 33

**FROM:** Chris Jiang, Chemist  
Product Science Branch  
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**THRU:** Karen P. Hicks, CTT Team Leader  
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**THRU:** Michele Wingfield, Branch Chief  
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9/16/03

**Product Formulation from label**

Active Ingredient(s)	% by wt.
n-Alkyl (C <sub>12</sub> 68%, C <sub>14</sub> 32%) ethylbenzyl ammonium chloride	3.00 %
n-Alkyl (C <sub>14</sub> 60%, C <sub>16</sub> 30%, C <sub>12</sub> 5%, C <sub>18</sub> 5%) benzyl ammonium chloride	3.00 %
Hydrogen peroxide	6.3 %

## BACKGROUND:

The registrant has submitted a product chemistry package in support of a "me-too" registration (of 63761-3) of an end-use disinfectant. The registrant is citing their own data because they claim that the proposed product and the registered product are similar. The package includes a Confidential Statement of Formula, a label, and MRID 460335-01 which includes 830 Series Part A data requirements.

## FINDINGS:

1. The concentrations of the active ingredients on the Confidential Statement of Formula (CSF dated July 9, 2003) are inconsistent with the label declaration. The name of the source of two active ingredients is [REDACTED]. In addition, the active ingredient of n-alkyl (C<sub>14</sub> 60%, C<sub>16</sub> 30%, C<sub>12</sub> 5%, C<sub>18</sub> 5%) benzyl ammonium chloride is typed correctly on the label; however, this ingredient is typed as n-alkyl (C<sub>14</sub> 60%, C<sub>16</sub> 30%, C<sub>12</sub> 5%, C<sub>18</sub> 5%) ethylbenzyl ammonium chloride on the CSF. [REDACTED]. The concentrations on the CSF and label should be listed to two places beyond the decimal point.
2. The registrant is applying for a "me-too" registration and has just submitted Group A data requirements. The proposed formulation is substantially different from the registered product so that all 830 Series 830 data requirements are necessary for registration. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]
3. On the CSF, the amount of [REDACTED] is mistyped. It should be typed as [REDACTED].
4. Because the label and the CSF are inconsistent, all 830 Series Part A data requirements are unacceptable because the Agency is unsure about the contents of the product.
5. The upper and lower certified limits for the source of the quaternary compounds must be [REDACTED] respectively. The upper and lower certified limits for the source of hydrogen peroxide must be [REDACTED], respectively. The lower certified limit for hydrogen peroxide must be 5.99.
6. The registrant must submit/resubmit all Series 830 Part B data requirements for end-use products to the Agency for review. All data requirements must be addressed and cannot be ignored. If a data requirement is not applicable, it must be stated as such.
7. Because the proposed product cannot be a "me-too" registration of 63761-3, the registrant must submit toxicity data for the proposed product.

8. Because the proposed product has public health claims and the registered product does not, efficacy data must be submitted to support the organisms that are declared on the label. Because the proposed product has public health claims, a one year GLP storage stability study must be submitted to the Agency for review.

9. The CSF for the activator is acceptable. Please submit the CSF for the finished product, that is, the CSF for the product after it has been activated.

**RECOMMENDATIONS:**

1. Product Science Branch of Antimicrobials Division finds this submission in support of the registration of 63761-I to be unacceptable for the reasons discussed in the findings. The registrant must remedy the discrepancies discussed in the findings before registration of this product can proceed.